RNK Products

510(k) SUMMARY
RNK Products
PCP-USB Stethoscope

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K132560

Submitter Information

Submitter: RNK Products
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RNK Products
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Date Prepared: October 9, 2013

Device Information

Name of Device	RNK PCP-USB Stethoscope
Common or Usual Name	Electronic Stethoscope
Classification Name	Electronic Stethoscope
Predicate Devices	RNK Products PCP/PC Stethoscope (K102893)

Device Description

The PCP-USB Stethoscope consists of a hardware element, the PCP-Chest Piece, and software elements consisting of some audio signal processing in the Streaming Stethoscope Over IP (sSOIP) Anywhere software on the end station PCs, communications software on the end station PCs (sSOIP Anywhere), and communications networking software on the Telemedicine Communications Server (TMCS), Relay Server and Stethoscope User Data (SUD) Server. It provides remote auscultation between a patient at one location and a clinician at another location.

The PCP-USB Chest Piece contains an embedded piezo sensor, audio amplifier Analog to Digital Converter (ADC) and Encoder to create a digitized stream, plus a USB interface to send that data to the PC. The PCP-USB Chest Piece derives its operating voltage from the 5v lead of the USB interface to the PC.

Under direction of the sSOIP Anywhere program in the PC, the digitized signal is formatted in the PC into IP packets for transport. Both the transmit end station (i.e. patient end) and the receive end station (i.e. clinician end) log into the TMCS, which indicates their availability for a connection.

In the sSOIP Anywhere program, the clinician at the receive end, selects a patient from a list of available patients and initiates a connection request to the TMCS, which passes on the request to the patient station. When the patient accepts the incoming connection request in the sSOIP Anywhere program, the TMCS facilitates a direct (peer-to-peer) connection between the two parties. If a direct connection is not possible, the TMCS facilitates a relay connection between the two parties through a Relay Server. No patient stethoscope data passes through the TMCS.

At the receive end PC, the sSOIP Anywhere program directs the acceptance of the IP packets, conversion of the digitized signal back to analog and presentation of the analog signal to the Headset port of the PC.

The TMCS receives information on users that are permitted to use the TMCS services from a SUD Server. That information would be entered into the SUD Server by the health care provider responsible for those users.

Intended Use

The PCP-USB Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Substantial Equivalence

The PCP-USB Chest Piece includes the same piezo sensor and the same audio amplifier as the predicate PCP/PC Chest Piece. But whereas the PCP/PC Stethoscope uses the Analog to Digital Converter (ADC) and Encoder of the PC's audio circuitry, the PCP-USB Chest Piece embeds those circuit elements within the chest piece head itself. Whereas the PCP/PC Chest Piece derives its operating voltage from the phantom voltage on the Microphone port of the PC, the PCP-USB derives its operation voltage from the 5v lead of the USB interface to the PC. The PCP-USB Stethoscope is substantially equivalent to the RNK Products, Inc. PCP/PC Stethoscope. Bench testing and clinical testing were performed to verify specifications and performance.

The sSOIP Anywhere software is an enhancement of the predicate sSOIP software such that working with the TMCS, SUD Server and Relay Server, IP connections can be accomplished

across Network Address Translation (NAT) boundaries, whereas sSOIP could only make IP connections between static IP addresses.

Both the PCP-USB Stethoscope and the predicate device successfully demonstrated conformance to IEC60601-1:2005 3rd Edition Medical Electrical Equipment Part 1: General Requirement for Safety and to EN60601-1-2, 2007/03, EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests. Since both devices use the same materials that a patient or clinician might touch, the biocompatibility analysis is the same. The PCP-USB Stethoscope passed the same auscultation performance tests as the predicate device both in bench testing and by clinicians.

The RNK PCP-USB Stethoscope has the same intended use, principles of operation and technological characteristics as the predicate devices. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 11, 2013

Rnk Products, Inc.
c/o Mr. Charles Abbruscato
C.E.O.
8247 Devereux Dr Ste 101
Melbourne, FL 32940 US

Re: K132560
Trade/Device Name: PCP-USB Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 4, 2013
Received: August 15, 2013

Dear Mr. Charles Abbruscato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

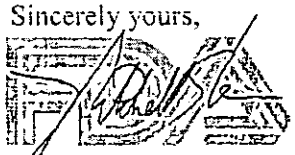
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132560

Indications for Use

510(k) Number (if known): K_____

Device Name: PCP-USB Stethoscope

Indications for Use:

The RNK PCP-USB Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Prescription Use: X OR Over-the-Counter Use _____
(Part 21 CRF 801 Subpart D) (Part 21 CRF 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)